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10/713,137	11/13/2003	Abdul Qadar Mohammad Pasha	09755-0018US1	9553

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EXAMINER	
SHAW, AMANDA MARIE	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 12/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/713,137	PASHA ET AL.	
	Examiner	Art Unit	
	Amanda M. Shaw	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 5-7 is/are rejected.

7)☒ Claim(s) 1-6 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Objections

1. Claim 1 is objected to because of the following informality: The phrase "risk to of" in the second to last line should read "risk of". Appropriate correction is required.

Claim 2 is objected to because of the following informalities: There is a period missing from the end of the claim. Also the phrase "selected from group" in the second line should read "selected from the group consisting of". Appropriate corrections are required.

Claim 3 is objected to because of the following informalities: There is a period missing from the end of the claim. Also the phrase "selected group comprising of" in the second line should read "selected from the group consisting of". Appropriate corrections are required.

Claim 4 is objected to because of the following informality: There is a period missing from the end of the claim. Appropriate correction is required.

Claim 5 is objected to because of the following informalities: There is a period missing from the end of the claim. Also the phrase "comprising of" in the second line should read "comprising". Appropriate corrections are required.

Claim 6 is objected to because of the following informality: There is a period missing from the end of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written Description rejection.

The claim is drawn broadly to encompass all of the nucleic acid vectors containing the allelic variants of the iNOS gene. The claim does not define the allelic variant with respect to its nucleotide identity or location. Accordingly, the claim encompasses allelic variants of the iNOS gene wherein the variants differ from the wild type sequence by including any number of insertions, deletions, or substitutions. The claim also includes splice variants of the iNOS gene.

The specification (page 6) teaches a single nucleotide polymorphism in the iNOS gene that can produce 3 different genotypes (e.g. AA, AG, and GG). This mutation occurs at the 19480 position of intron 7. The specification also teaches that this mutation is associated with the occurrence of high altitude pulmonary edema (HAPE). The prior art of Johannesen et al (Page 2792) teach 10 polymorphisms in the iNOS gene (e.g. an A→G mutation at position 300 with respect to Genbank Accession No. X85766). However, Johannesen et al do not teach any associations between the

polymorphisms they studied and HAPE. While vectors comprising the A/G nucleotide variation at the 19480 position of intron 7 of the iNOS gene meet the written description requirements of 35 U.S.C. 112, first paragraph, the specification does not disclose and fully characterize a representative number of allelic variants of the iNOS gene.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that 'applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that 'An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, one member of the genus of iNOS

nucleotide variations has been identified in the specification. The prior art teaches that there are at least 10 polymorphisms in the iNOS gene. No additional nucleotide variations have been disclosed in the specification or prior art. It is then determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g. restriction map, biological activity of an encoded protein product, etc.). In the instant case, no such identifying characteristics have been provided for any of allelic variants or mutant iNOS nucleic acids. Yet, the claims as written are inclusive of a potentially large genus of mutations in the iNOS gene. While one could contemplate a nucleotide substitution, deletion or addition at each and every position in the iNOS gene, such nucleotide variations are not considered to be equivalent to specific nucleotide variations associated with HAPE. Rather, mutations in the iNOS gene associated with HAPE represent a distinct group of nucleotide variations, which are expected to occur at only specific locations within the gene and consist of specific nucleotide alterations. Accordingly, knowledge of the sequence of the wild-type gene does not allow the skilled artisan to envision all of the contemplated polymorphisms encompassed by the claimed genus. Conception of the claimed invention cannot be achieved until reduction to practice has occurred, regardless of the complexity or simplicity of potential methods for isolating additional nucleotide variations. As stated in *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. LTD*, 25 USPQ2d 1016, one cannot describe what one has not conceived.

Further, the specification only teaches one mutation present in intron 7 of the iNOS gene. The specification does not teach any mutations in the remaining introns or in any exons, or 5' or 3' non-coding sequences and does not teach any gross chromosomal rearrangements in the iNOS gene.

For these reasons, Applicants have not provided sufficient evidence that they were in possession, at the time of filing, of the invention as it is broadly claimed and thus the written description requirement has not been satisfied for the claims as they are broadly written. Applicants attention is drawn to the Guidelines for the Examination of Patent Applications under 35 U.S.C. 112, ¶ 1 'Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

3. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid vector comprising a human iNOS gene wherein said iNOS gene contains a G at nucleotide position 19480, does not reasonably provide enablement for the nucleic acid vectors containing all of the allelic variants of the iNOS gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following factors have been considered in formulating this rejection (*In re Wands,* 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988): the breadth of the claims, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, the amount of direction or guidance

presented, the presence or absence of working examples of the invention and the quantity of experimentation necessary.

Breadth of the Claims:

The claim is drawn broadly to nucleic acid vectors containing the allelic variants of the iNOS gene. The claim does not define the identity or position of all of the nucleotide variants of the iNOS gene. Accordingly, the claim encompasses allelic variants of the iNOS gene wherein the variants differ from the wild type sequence by including any number of insertions, deletions, or substitutions. The claim also includes splice variants of the iNOS gene.

Nature of the Invention

The claim is drawn to all of the nucleic acid vectors, which contain allelic variants of the iNOS gene. The invention is in a class of inventions which the CAFC has characterized as 'the unpredictable arts such as chemistry and biology" (Mycolgen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Federal Circuit 2001)).

Teachings in the Specification and State of the Art:

The specification cites GenBank Accession No. NT_010799 as teaching the wild type iNOS gene sequence. The specification (page 6) teaches one mutation in the iNOS gene that can produce 3 different genotypes (e.g. AA, AG, and GG). This mutation occurs in intron 7 of the iNOS gene, at position 19480 with respect to the iNOS genomic DNA sequence of NT_010799. The specification also teaches that this mutation is associated with the occurrence of HAPE. Further, the specification teaches that variants of the iNOS gene are to be used to diagnose HAPE (see, e.g., page 5).

Accordingly, the specification has enabled for a nucleic acid vector comprising a human iNOS gene wherein said iNOS gene contains a G at nucleotide position 19480. The specification only teaches this mutation of the iNOS gene, wherein the presence of said mutation indicated that said subject is at risk of developing HAPE. The specification does not teach any mutations in the remaining introns or in any exons, or 5' or 3' non-coding sequences and does not teach any gross chromosomal rearrangements in the iNOS gene which are associated with HAPE.

The Predictability or Unpredictability of the Art and Degree of Experimentation:

The art of identifying novel variants in iNOS gene which to allow for the genetic predisposition of HAPE is highly unpredictable. Knowledge of the sequence of the wild type iNOS gene does not allow one to immediately envision additional mutations in the iNOS gene that are associated with HAPE.

The iNOS gene is expected to contain numerous polymorphisms, particularly given the size of the gene. This finding is supported by the teachings Xu in that Xu teaches that there is a positive association between human NOS2A promoter polymorphisms and malaria susceptibility (see page 379 of Xu). However, the specification does not teach a predictable means for identifying additional variations associated with HAPE or for distinguishing between variations associated with HAPE and naturally occurring polymorphisms. Without extensive information regarding the structure-function relationship between the iNOS gene and HAPE, it is highly unpredictable as to what would be the identity of additional mutant, allelic, or splice variants which would be associated with HAPE. Thus, one cannot readily anticipate the

effect of a polymorphism or mutation on the function or activity of the iNOS gene or the protein encoded thereby.

Further, it is unpredictable as to what would be the identity of iNOS variants from other organisms and whether the nucleic acid variants would be associated with HAPE. The specification does not teach homologues of the iNOS gene in a representative number of different organisms. The specification also does not teach any other organisms which have an iNOS phenotype similar to that observed in humans, such that one would expect that mutations in the homologous iNOS genes would lead to HAPE like disorders in other organisms. In the absence of information regarding the functional properties of the iNOS gene and the disclosed mutations in this gene, it is unpredictable as to whether the iNOS gene, and particularly the mutation at the 19480 position of intron 7, will also be present in other organisms and will be diagnostic for an HAPE phenotype.

Amount of Direction or Guidance Provided by the Specification:

The specification teaches one variant in the iNOS gene, which is associated with HAPE. However, the iNOS gene is significantly large, comprising about 40Kb and spanning 27 exons. To identify additional variants of the iNOS gene that are diagnostic for HAPE would require extensive experimentation. For example, such experimentation may involve sequencing the iNOS gene of affected individuals having HAPE, sequencing the iNOS gene of control individuals which do not have HAPE, comparing the sequences of these two groups, and then identifying variations which are present only in the affected group and not in the control group. Such random, trial by error

experimentation is considered to be undue. While methods for sequencing genes are known in the art, such methods provide only the general guidelines that allow researchers to randomly search for mutations that may linked to a disease. The results of performing such methodology are highly unpredictable. The specification has provided only an invitation to experiment. The specification does not provide a predictable means for identifying additional variants of the iNOS gene and using these variants to identify individuals susceptible to developing HAPE.

Working Examples:

Again, the specification teaches a nucleic acid vector comprising a human iNOS gene wherein said iNOS gene contains a G at nucleotide position 19480. There are no working examples provided in the specification in which nucleic acid vectors comprising other allelic variants are used.

Conclusions:

Case law has established that '(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. *In re Fisher,* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that '(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". The amount of guidance needed to enable the invention is related to the amount of knowledge in the art as well as the predictability in the art. Furthermore, the Court in *Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001 held that '(I)t is the specification, not the knowledge of

one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement".

In the instant case, the claims do not bear a reasonable correlation to the scope of enablement because the specification teaches 1 mutation within the iNOS gene which is associated with HAPE. The specification does not teach a representative number of additional variants, including insertions, deletions, substitutions or splice variants, or gross chromosomal rearrangements which are associated with HAPE. The specification teaches a mutation present at the 19480 position of intron 7. However, the specification does not teach any mutations in the remaining introns, or in any exons or 5' or 3' non-coding sequences. Further, the specification does not teach how to use all variations in the iNOS gene as a means for predicting susceptibility to HAPE. Additionally, the disclosure of a single organism, humans, in which mutations in the iNOS gene are correlated with HAPE is not representative of the broadly claimed genus of iNOS nucleic acid variants obtained from any mammalian and non-mammalian subject. Accordingly, although the level of skill in the art of molecular biology is high, given the lack of disclosure in the specification and in the prior art and the unpredictability of the art, it would require undue experimentation for one of skill in the art to make and use the invention as broadly claimed.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is incomplete since it refers to a kit comprising of primers and probes, but only defines the primers being used.

Claim 6 is indefinite because it is unclear as to whether the primer pair consists of a forward primer consisting of SEQ ID NO:2 and a reverse primer consisting of SEQ ID NO: 3 or whether the primer pairs include a forward primer comprising SEQ ID NO: 2 or a reverse primer comprising SEQ ID NO: 3.

Claim 7 recites the limitation "the allelic variants". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Xu et al (Page 784).

Regarding Claim 7, the genomic sequences of Xu et al were deposited as GenBank Accession No's X81701-X81702 and X85759-X85781 (Page 784). In

particular, the vector of Xu et al comprises a nucleic acid which includes an A at position 19480 of the genomic sequence. It is a property of nucleotide position 19480 that this position is variable. Accordingly, Xu teaches a nucleic acid vector comprising an allelic variant of the iNOS gene.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al (EMBL Data Bank X85766) in view of Johannesen et al (Page 2792).

Xu et al teach the sequences of exon 8, intron 8, and exon 9 of the iNOS gene (EMBL Data Bank X85766). The disclosed sequences of SEQ ID No. 2 and SEQ ID No. 3 are found within the sequences taught by Xu. SEQ ID No. 2 begins at the 159 position and SEQ ID No. 3 begins at the 397 position and is the inverse complement of nucleotides 397-416. While Xu teaches nucleic acids comprising SEQ ID NO: 2 and 3, Xu does not teach a pair of primers comprising SEQ ID NO: 2 and 3.

However, amplification of a target gene using forward and reverse primers was well known in the art at the time the invention. It was also well known in the art at the time of the invention that amplified nucleic acids can be used in sequencing assays to detect mutations. Johannesen et al teach nucleotide amplification of the entire human iNOS gene using PCR followed by single stranded conformation polymorphism and

sequencing to detect mutations (Page 2792). Johannesen et al exemplifies primers useful for amplifying each of the 27 exons of the iNOS gene (see, e.g., Table 1). Johannesen et al also teach polymorphisms that were identified in the iNOS gene, including an A → G polymorphism at position 300 of Genbank Accession No. X85766.

While the combined teachings of Xu et al and Johannesen et al do not teach primers limited to SEQ ID NO: 2 and 3, it was well known in the art at the time the invention was made that oligonucleotide primers of different lengths and base composition could be used to amplify nucleic acid sequences. Designing primers which are equivalents to those taught in the art is routine experimentation. The parameters and objectives involved in the selection of primers were well known in the art at the time the invention was made. Moreover, software programs were readily available which aid in the identification of conserved and variable sequences and in the selection of optimum primer pairs. The prior art is replete with guidance and information necessary to permit the ordinary artisan to design additional primers for the amplification of iNOS intron and exon sequences. The ordinary artisan would have been motivated to have designed additional primers for amplifying intron 7 sequences of the iNOS so as to have provided primers which would amplify and allow for the detection of new variable sequences. Further, the ordinary artisan would have had more than a reasonable expectation of success of obtaining additional primers for amplifying iNOS sequences. Thus, for the reasons provided above, the primers of SEQ ID NO: 2 and 3 would have been obvious to one of ordinary skill in the art.

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al (EMBL Data Bank X85766) in view of Johannesen et al and further in view of Ahern (page 22).

The teachings of Xu et al and Johannesen et al are presented above. The combined references do not teach packaging the primers into a kit. However, reagent kits for performing DNA detection assays were conventional in the field of molecular biology at the time the invention was made. In particular, Ahern discloses the general concept of kits for performing detection methods and teaches that kits provide the advantage of pre-assembling the specific reagents required to perform an assay and ensure the quality and compatibility of the reagents to be used in the assay. Ahern (page 22) also teaches that kits provide the benefits of cost-effectiveness and time efficiency. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the primers of SEQ ID No. 2 and SEQ ID No. 3 in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to amplify iNOS sequence to identify additional mutations or polymorphisms in the iNOS gene.

It is noted that the recitation of "for the detection of SNP genotypes having predisposition to high altitude pulmonary edema (HAPE)" merely sets forth the intended use or purpose of the claimed kits, but does not limit the scope of the claims. As stated in *Pitney Bowes Inc. v. Hewlett-Packard Co.*, 182F.3d 1298, 1305, 51 USPQ2d 1161, 1166 (Fed Cir. 1999), if the body of the claim sets forth the complete invention, and the preamble is not necessary to give "life, meaning and vitality" to the claim, "then

the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation."

8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johannesen et al (Page 379) in view of Billiar et al (U.S. Patent 5,658,565).

Regarding Claim 7, Johannesen et al teach an A → G polymorphism that was identified in the iNOS gene, at position 300 of Genbank Accession No. X85766 (Table 1).

Regarding Claim 7, Johannesen et al do not teach nucleic acid vectors containing allelic variants of the iNOS gene. However, cloning a mutation into a vector for the purpose of expressing a protein to determine the effect of the mutation on the expression of the protein or the activity of the protein was well known in the art at the time the invention was made. In particular, Billiar et al disclose a method of converting human iNOS cDNA clones to a plasmid vector for the benefit of obtaining a full length cDNA clone which can be sequenced and expressed as a protein in a sequencing system (Column 4 lines 50-67). Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to insert the mutant DNA fragments into a vector for the expected benefits of being able to obtain a full length cDNA which can be sequenced and expressed by a protein in a sequencing system to determine the effects of the mutation.

Conclusion

9. No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634
December 14, 2005

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER